MAR 1 2002

## XIV. 510(k) Summary

Pursuant to 512(i)(3)(A) of the Food, Drug and Cosmetic Act, TeleMed Systems, Inc. is required to submit with this Premarket Notification either an "...adequate summary of any information respecting safety and effectiveness or state that information will be made available upon request of any person." TeleMed Systems chooses to submit a summary of the safety and effectiveness information. The summary is as follows:

| | |
|---|---|
| **Trade Name:** | 3-Lumen Duralon Occlusion Balloon |
| **Owner/Operator:** | TeleMed Systems, Inc.<br>8 Kane Industrial Drive<br>Hudson, MA 01749 |
| **Manufacturing Site:** | TeleMed Systems, Inc.<br>8 Kane Industrial Drive<br>Hudson, MA 01749 |
| **Device Generic Name:** | Occlusion Balloon Catheter |
| **Classification:** | According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II, Performance Standards (FGE). |
| **Predicate Devices:** | TeleMed Systems Occlusion Balloon (K901427) |

**Product Description:**
The 3-Lumen Occlusion Balloon consists of a compliant polymer balloon mounted on a plastic shaft. The shaft has 3 internal lumens, each of which terminates in a proximal connector and connection tube. The lumens are used for balloon inflation, guidewire passage and distal fluid injection.

**Indications for Use:**
The TeleMed Systems 3-Lumen Occlusion Balloon is indicated for use in fluoroscopic examination of and removal of stones from the bile duct.

**Safety and Performance:**
This submission is a Special 510(k): Device Modification as described in FDA's guidance document entitled "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Pre-Market Notifications." In support of this 510(k), TeleMed Systems, Inc. has provided certification of compliance to 21 CFR 820.30 Design Control requirements, and a description of the internal Risk Analysis procedure. Design Verification and Validation testing has been performed to ensure that the modified device meets design specifications; V&V testing has been summarized in this Special 510(k). The proposed 3-Lumen Occlusion Balloon has been compared to the TeleMed Systems' Occlusion Balloon as cleared in K901427.

**Conclusion:**
Based on the indications for use, technological characteristics, comparison to a predicate device and V&V testing results, the TeleMed Systems, Inc. 3-Lumen Occlusion Balloon Catheter has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 2002

Mr. Michael Carroll
President and CEO
TeleMed Systems, Inc.
8 Kane Industrial Drive
HUDSON MA 01749

Re: K013737
Trade/Device Name: TeleMed Systems, Inc.
3-Lumen Occlusion Balloon
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: January 30, 2002
Received: January 31, 2002

Dear Mr. Carroll:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | |
|---|---|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## SPECIAL 510(k) PREMARKET NOTIFICATION: DEVICE MODIFICATION



510(k) Number (if known): K013737

Device Name: TeleMed Systems, Inc. 3-Lumen Occlusion Balloon

Indications for Use:

The TeleMed Systems 3-Lumen Occlusion Balloon Catheter is indicated for use in fluoroscopic examination of and removal of stones from the bile duct.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David C. Dysert

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013737

Prescription Use ✓ OR Over-the -Counter Use ____
(Per 21 CFR 801.109)